

Keep Watch Of French Authority's Pharma Sector Inquiry

Law360, New York (March 20, 2013, 1:31 PM ET) -- On Feb. 25, 2013, the French Competition Authority announced the launch of a sector inquiry in the pharmaceutical sector. The authority plans to issue its preliminary findings on or about July 2013 in order to deliver its final report and recommendations before the end of 2013.

The French Competition Authority has the power to open inquiries in specific sectors in order to evaluate competition intensity, identify potential issues and make recommendations to improve the functioning of the market concerned.

In recent years, the French Competition Authority has been very active on this front, publishing reports covering sectors such as online commerce, auto spare parts, online advertising, food retail, etc., with a strong impact on pending and/or subsequent public and private enforcement actions.

The Scope of the Inquiry

In the road map that was just published, the French Competition Authority explained that the investigation will assess if and how recent regulatory evolutions have effectively fostered competition in this sector. The inquiry will focus on the competitive structure and practices at each level of the distribution chain of pharmaceutical producers, wholesalers and pharmacists.

- The authority first intends to assess the scope for competitive pricing on medicines that are reimbursed, and the investigation will include the whole pricing formation process between producers, wholesalers and pharmacists as far as nonreimbursed medicines are concerned.
- The wholesaling system applicable in France, with “grossistes-répartiteurs” between producers and pharmacists, will also be investigated, including cross-borders aspects (competitive pressure exercised by wholesalers through imports from and exports to other European Union member states). The authority has started to address this subject with an opinion No. 12-A-18, released on July 20, 2012, recommending that restrictions to such cross-border trade be limited to the necessary minimum.

- The inquiry will also cover practices that are likely to delay generic entries and could eventually include recommendations to originator companies to adopt “internal prevention programs” to avoid anticompetitive practices as well as recommendations to improve regulations to stimulate competition between originator and generic medicines. It may be noted that the authority is currently investigating several cases concerning complaints against originator companies (see decisions No. 10-D-16 and 09-D-28).
- Nonreimbursed medicines are also included in the scope of the investigation, considering the recent price evolution of those products, and the authority will notably assess the reality of price competition between manufacturers, as well as price and service competition at the level of pharmacists.
- The authority will finally focus on the development of online sales. In a recent opinion (Avis No. 12-A-23), the authority has advocated extending French legislative proposals transposing the EU Directive No. 2011/62 to all medicines that are not subject to medical prescription. This recommendation has not been followed so far, but the entry into the force of these new provisions has been suspended for legality issues by the French Administrative Supreme Court on Feb. 14, 2013. The sector inquiry will also provide an opportunity to assess how the directive has been transposed in other member states and the conditions that need to be ensured for proper development of online sales.

The Implications of a Sector Inquiry

As it has done in a number of cases — and it will do so here — the authority first publishes preliminary findings for comments, before issuing its final enquiry report, based on the information gathered through requests for information and hearings conducted by its investigation services.

The final report details the relevant competition assessment to be made of a number of practices in the sector at hand and includes specific recommendations to companies and/or to the government, where legislative or regulatory changes appear necessary. If possibly uncompetitive practices are uncovered, individual infringement proceedings can also be opened by the authority.

The authority’s inspection powers do not explicitly apply to sector inquiries, with the consequence that inspections — as it was done in the EU pharmaceutical inquiry — are not expected here, but companies are to cooperate with the inquiry and provide all information requested in that purpose.

The provision of incorrect or misleading information or a refusal to provide the information requested may expose companies to a fine of up to, respectively, 1 percent or 5 percent of their global total turnover under article L 464-2, V of the Commerce Code.

Lessons Learned from the EU Pharmaceutical Sector Inquiry

As it did in the EU pharmaceutical sector inquiry in 2008 to 2009, the French investigation will address practices delaying the entry of generic products, but it will largely focus on pricing and distribution issues, though the EU inquiry was rather intellectual property-oriented.

To date, the European Commission has opened several formal procedures under Article 102 TFUE (abuse of dominance) against practices that might have had the object or effect of delaying generic drugs entry (COMP/39.612 — Perindopril, COMP/39.226 — Citalopham, COMP/39.686 — Modafinil, COMP/39.685 — Fentanyl).

Following up on the recommendations of its final report, the European Commission also launched three successive patent settlements monitoring exercises designed to identify potentially problematic settlements from an antitrust perspective, in particular, those that limit generic entry against payment from an originator to a generic company.

Finally, the commission recommended the introduction of an EU patent and a unified, specialized patent litigation system in order to improve the fragmented patent system, which currently causes legal uncertainty in patent disputes all over the EU, a project which is about to become reality.

Link to the decision No.13-SOA-01 dated Feb. 25, 2013, launching the sector inquiry:
http://www.autoritedelaconurrence.fr/user/standard.php?id_rub=483&id_article=2051

--By Nathalie Jalabert Doury, Kiran Desai, Robert Klotz, Jens Peter Schmidt and Gillian Sproul, Mayer Brown LLP

Nathalie Jalabert Doury is a partner in the firm's Paris office. Kiran Desai, Robert Klotz and Jens Peter Schmidt are partners in the Brussels office. Gillian Sproul is a partner in the London office.

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